

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of 2009 Iowa Code Supplement section 124.212B(8) and Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, “Controlled Substances,” Iowa Administrative Code.

The proposed amendments were approved at the March 9, 2010, regular meeting of the Board of Pharmacy.

These proposed amendments clarify the form of identification to be reviewed by a pharmacist prior to dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription and provide that purchase records be recorded in the real-time electronic repository established by the Governor’s Office of Drug Control Policy pursuant to 657—Chapter 100 (proposed herein as **ARC 8666B**). The amendments also establish the format and content of an alternate record to be maintained if the real-time electronic repository is temporarily unavailable for use and provide for a notice to purchasers warning of criminal penalties if a purchaser is found in violation of laws relating to the purchase of ephedrine, pseudoephedrine, or phenylpropanolamine.

Interested parties may submit written comments on the proposed amendments not later than 5 p.m. on April 27, 2010, to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Des Moines, Iowa 50309; by E-mail to terry.witkowski@iowa.gov; or via facsimile to (515)281-4609.

These proposed amendments are not subject to waiver.

These amendments are intended to implement 2009 Iowa Code Supplement sections 124.212, 124.212A, 124.212B and 124.213 and Iowa Code section 155A.13.

The following amendments are proposed.

ITEM 1. Amend subrule 10.32(5) as follows:

10.32(5) Identification. The pharmacist shall require every purchaser under this rule to present a current, valid government-issued photo identification, including proof of age when appropriate. The pharmacist shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

ITEM 2. Amend subrule 10.32(6) as follows:

10.32(6) Record. ~~A legible dispensing record shall be created and maintained for the dispensing of ephedrine, pseudoephedrine, and phenylpropanolamine products pursuant to this rule. Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor’s office of drug control policy pursuant to 657—Chapter 100. If the real-time electronic repository is unavailable for use, the purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).~~

~~a. Record Alternate record contents.~~ The alternate record shall contain the following:

- (1) The name, address, and signature of the purchaser.
- (2) The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.
- (3) The date and time of the purchase.
- (4) The name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the product.

~~b. Record Alternate record format.~~ The record shall be maintained using one of the following options:

- (1) A hard-copy record ~~maintained in a bound logbook (i.e., with pages sewn or glued to the spine).~~
- (2) A record in the pharmacy's electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.
- (3) A record in an electronic data collection system that captures each of the data elements required by this subrule. ~~The electronic data collection system shall be~~ and that is capable of producing a hard-copy printout of a record.

c. PTS records retrieval. Pursuant to 657—subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

ITEM 3. Amend subrule 10.32(7) as follows:

10.32(7) Notice required. The pharmacy shall ensure that the following notice shall be included in the logbook required pursuant to subrule 10.32(6) or shall be is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products and that the notice is displayed with or on the electronic signature device or is displayed in the dispensing area and be visible to the public:

“WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than \$250,000 if an individual or \$500,000 if an organization, imprisoned not more than five years, or both.”